Approved by:

EPA Reviewer:

Signature:
Date: 12/1/92

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-1; Acute oral toxicity in rats

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423168-14

PC Number:

TEST MATERIAL: HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l

SYNONYM(S): HOE 039866 OH SL06 A302

SPONSOR: Hoechst Celanese Corp., Somerville, NJ

STUDY NUMBER: 88.0406

TESTING FACILITY: Pharma Research Toxicolgy and Pathology, Frankfurt, Germany

TITLE OF REPORT: Testing for Acute Oral Toxicity in the Male and Female Wistar Rat.

AUTHOR(S): K. Diehl and K. Leist

STUDY COMPLETED: May 19, 1988

CONCLUSIONS: Acute oral LD_{50} in males: >5000 mg/kg
Acute oral LD_{50} in females: >2000 and <4000 mg/kg
Acute oral LD_{50} in sexes combined: Not determined.

CORE CLASSIFICATION: Core Guideline. This study satisfies the guideline requirements (81-1) for an acute oral toxicity study.

TOXICITY CATEGORY: III (Caution).

A. MATERIALS

Test Compound

Test material: HOE 039866 - Liquid, Water-Soluble Concentrate 60(g/l)
Identification number: Sample no. Koc 2391, Batch no. Ko 800-V1
Formulation: 6% w/w Glufosinate ammonium
Purity: see above
Physical description: Blue liquid
Storage condition: 4°C in refrigerator and in darkness
Stability: Certificate of analysis dated Mar. 15, 1988.

Dose levels: 2,000; 4,000; 5,000 mg/kg

Controls:

Test Animals

Species: Rat
Strain: Wistar Hoe: WISKf(SPF71)
Source: HOECHST AG, Kastengrund, Germany
Sex: Males and females
Age: Males approximately 6 weeks, Females approximately 9 weeks
Weight: Males 214-232 g; Females 196-223 g Test day
No. animals/dose: 2000 and 4000 mg/kg: 5 females; 5000 mg/kg: 5/sex

Environmental conditions: Temperature: 22±3°C
Relative Humidity: 50±20%
Photoperiod: 12 hours

B. TEST PERFORMANCE

Animals fasted: 16 hours

Dosing: Once __x__; Other _____ (describe)

Observation period: 14 days

Observation frequency: Six times on day 0 and daily thereafter

Body weight interval: 7 days

Gross pathology: YES __x__; NO _____

Histopathology: YES _____; NO __x__

C. RESULTS

Mortality: Mortality results are summarized below.

Dosage (unit) mg/kg	(Number Dead / Number Tested)		
	Males	Females	Combined
2000		0/5	
4000		4/5	
5000	0/5	4/5	4/10

Animals died between days 1 and 9 of treatment.

Clinical Observations: Males exhibited some non-specific clinical signs. Observations for females included reduced spontaneous activity, contracted flanks, squatting position, high legged gait, prone or lateral position, ataxic gait, crawling locomotion, increased or decreased respiratory rate, irregular breathing, abnormal respiratory sounds, gasping salivation, blood crusted snout, narrowed or closed palpebral fissures, poor general condition, trembling, piloerection, tonoclonic/rolling spasms, cannabalism, reduced to negative placing reflex, reduced paw-pinch reflex, Straub tail, straddling of legs, bizarre movements, and reduced body temperature.

Clinical signs began at the first hour. Surviving animals were free of clinical signs after 3 days.

Body Weights: Females dosed at 4000 and 5000 mg/kg showed impaired bodyweight gain.

Gross Necropsy: Findings for animals found dead during the study included small intestine filled with blackish-brown/yellow fluid, advanced autolysis, and cannabalism. Some of the animals killed at study termination exhibited reddened adrenals and kidneys with dark patches.

LD_{50} Determination: The estimated acute oral LD_{50}, was >5000 mg/kg in males and >2000 mg/kg in females. These values correspond to Toxicity Category: III (Caution).

D. REVIEWER'S COMMENTS: We assess in agreement with the study author that the LD50 for rats for HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l was >2000 mg/kg for females and >5000 mg/kg for males.

E. QUALITY ASSURANCE MEASURES

Was the test performed under GLPs? YES __x__; NO ____
A Quality Assurance Statement, signed Aug. 24, 1988 was submitted.

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager: 23
MRID No.: 423168-15

Reviewer: Ian Blackwell
Report Date: 4-7-88
Report No.: A38670

Testing Laboratory: Pharma Research Toxicology and Pathology
Author(s): Dr. K.-H. Diehl, and Dr. K.-H. Leist

Quality Assurance (40 CFR §160.12): Included

Test Material: HOE 039866 OH SL06 A302 (Arise Herbicide)

Species: Wistar rat
Weight: 200 to 242 g
Age: males ≈ 8 weeks; females ≈ 10 weeks
Source: HOECHST AG, Kastengrund, SPF breeding colony

Summary:

1. **LD_{50} (mg/kg):** **Males** > 4000 mg/kg
Females > 4000 mg/kg
Combined > 4000 mg/kg

2. **The estimated LD_{50} is** greater than 4000 mg/kg.

3. **Tox. Category:** III **Classification:** core-minimum

Procedure (Deviation From §81-2):
The exposure area was covered with aluminum foil.

Results:

Reported Mortality

DOSAGE	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
4000 mg/kg	0/5	0/5	0/10

Signs of toxicity: squatting position, increased spontaneous activity, irregular breathing; dry, chapped skin with fine and coarse scales.

Gross Necropsy Findings: The only abnormality was dark patches on the kidneys.

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DER 153-98

DATA EVALUATION REPORT

Glufosinate-Ammonium; Soluble Concentrate; 60 g/l

Study Type: Acute Inhalation Toxicity

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer Laura Kolb Date 9/23/92
Laura Kolb

QA/QC Manager William L McLellan Date 9/24/92
William McLellan

Contract Number: 68D10075
Work Assignment Number: 1-133
Clement Number: 1-133-197
Project Officer: James Scott

Approved by:

EPA Reviewer:

Signature: Lynn D. Blackwell
Date: 12/1/92

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-3; Acute inhalation toxicity

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423168-16

PC Number:

TEST MATERIAL: Glufosinate-Ammonium; Soluble Concentrate; 60 g/l, Arise™ Grass and Weed Killer Concentrate

SYNONYM(S): Code: HOE 039866 OH SL06 A306/A308

SPONSOR: Hoechst Celanese Corp., Somerville, NJ

STUDY NUMBER: 90.1219

TESTING FACILITY: Pharma Development Toxicology, Frankfurt, Germany

TITLE OF REPORT: Testing for Acute Aerosol Inhalation Toxicity in the Male and Female SPF Wistar Rat 4-Hour LC50

AUTHOR(S): T. Hoffman and R. Jung

STUDY COMPLETED: May 9, 1991

CONCLUSIONS: Acute inhalation LC_{50} in males: 2.45 mg/L
Acute inhalation LC_{50} in females: 2.01 mg/L
Acute inhalation LC_{50} in sexes combined: 2.19 mg/L

CORE CLASSIFICATION: Core Guideline. This study satisfies the guideline requirements (81-3) for an acute inhalation toxicity study.

TOXICITY CATEGORY: III (Caution).

A. MATERIALS

Test Compound

Test material: Clufosinate-Ammonium; Soluble Concentrate; 60 g/l
Identification number: Code: HOE 039866 OH SL06 A306/A308;
Sample no. Koc/EK 797
Formulation: 6.2% w/w Glufosinate ammonium
Purity: See above
Physical description: Blue liquid
Storage condition: At 20°C in a fume cupboard
Stability: Analysis date Nov. 14, 1990

Dose levels: 1.05, 1.31, 2.93 and 4.52 mg/L

Controls:

Test Animals

Species: Rat
Strain: Wistar Hoe: WISKf(SPF71)
Source: HOECHST AG, Kastengrund, Germany
Sex: Male and female
Number animals: 35
Age: 8-10 weeks
Weight: Males, 187-204 g; Females, 181-210 g; Test day
No. animals/dose: 5/sex (except 40 1.05 mg/L: 5 females)
Environmental conditions: Temperature: 22 ± 2° C
Relative Humidity: 50 ± 20%
Photoperiod: 12 hours

B. TEST PERFORMANCE

Inhalation chamber: The chamber was a stainless steel and glass cylinder with a 60 liter volume, standing in a vent pipe with a volume of 4 m_3. Plastic tubes leading into the chamber were arranged to permit only the nose of the animal to enter the chamber.

Dose preparation/Generation of test atmospheres: The aerosol was generated by pumping air through an oil separation filter and an absolute filter; then air was pumped at a pressure of 4 bar into a nozzle with a supply tube. The air supply at the nozzle was maintained at 800 l/h. The compound was then injected into the nozzle by a continous infusion apparatus and the primary aerosol particles passed into the exposure chamber. A suction device at the bottom of the exposure chamber drew off the aerosol at 1100 l/h through a washing flask/10% sodium hydroxide, a flask/cotton wool, a Buehler filter and then a flask/calcium chloride.

Analytical determinations: Gravimetric analysis of the aerosol concentration in the breathing zone was done at 15 minute intervals by collecting particles on a 0.65 um membrane filter at an airflow rate of 1.25 m/second. Chemical analyses of the active ingredient on the filters

was performed by HPLC and values connected to amount of test substance based on the percent of active ingredient in the formulation.

Dose Level mg/L	MMAD (um)	GSD	% particles <3.0 microns	% particles <1.0 micron
4.52	1.22	1.91	92 first sample	38 first sample
2.93	1.36	1.82	90 first sample	31 first sample
1.31	1.89	1.93	76 only sample	17 only sample
1.05	1.64	1.87	83 first sample	22 first sample

Chamber monitoring: Airflow, CO, CO_2, O_2, temperature, and humidity were meausured continuously throughout the exposure.

Oxygen content was at least 20%. Temperature ranged from 19-21°C and relative humidity was 100%.

Particle size determination: Particle size was determined twice per dose (except 1.31 mg/L: once) using a Andersen 7 stage cascade impactor. Sampling was done at a volume of 9.5 liters per minute resulting in a flow velocity of 1.25 m/s.

Exposure period: 4 hours

Observation period: 14 days (except males at 4.52 mg/L: 21 days)

Observation frequency: Frequently on day of exposure and twice daily thereafter

Body weight interval: 7 days

Gross pathology: YES __x__; NO _____

Histopathology: YES _____; NO __x__

C. RESULTS

Mortality: Mortality results are summarized below.

Dosage (unit) mg/L	(Number Dead / Number Tested)		
	Males	Females	Combined
4.52	4/5	5/5	9/10
2.93	3/5	3/5	6/10
1.31	1/5	0/5	1/10
1.05		2/5	

Time of death: Deaths occurred between 210 minutes and 11 days.

Clinical Observations: Observations included irregular respiration, sibilant rales, panting, gasping, sneezing, narrowed and closed palpebral fissures, uncoordinated/stilted/ataxic gait, ataxia, stupor, trembling, reduced paw reflex to pinching, reduced or absent placing reaction, decreased spontaneous activity, increased fright reaction, agressiveness, ruffled and bristling coat, straub tail, blood encrusted lid margin/nose/snout, nasal discharge, sunken flanks, squatting posture, prone and lateral position, straddling hind limbs, gnawing forelimb, poor general condition, very poor nutritive state, and diarrhea.

Body Weights: Body weight development was impaired in some animals of both sexes during the first week. By the end of the study all animals had surpassed their original weight.

Gross Necropsy: Findings for animals found dead during the study include stomach and small intestine full of gas, and lungs discolored and patchy with foam escaping after dissection. Autopsy of surviving animals revealed no abnormalities.

LC_{50} Determination: The estimated acute inhalation LC_{50}, calculated by probit analysis using the Linder and Weber method, was approximately 2.45 mg/L (1.07-4.91) in males and 2.01 (1.03-3.96) mg/L in females; the acute inhalation LC_{50} in sexes combined was 2.19 (1.41-3.27) mg/L. These values correspond to Toxicity Category: III (Caution).

D. REVIEWER'S COMMENTS: We assess in agreement with the study authors that the acute inhalation LC50 for rats for Glufosinate-Ammonium; Soluble Concentrate; 60 g/l was 2.19 mg/L.

E. QUALITY ASSURANCE MEASURES

Was the test performed under GLPs? YES _x_; NO ____
A quality Assurance Statement, signed Sept. 7, 1991 was submitted.

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DER133-99

DATA EVALUATION REPORT

HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l

Study Type: Primary Eye Irritation in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer Laura Kolb Date 9/23/92
Laura Kolb

QA/QC Manager William L McLellan Date 9/24/92
William McLellan

Contract Number: 68D10075
Work Assignment Number: 1-133
Clement Number: 1-133-198
Project Officer: James Scott

Approved by:

EPA Reviewer:

Signature:
Date: 12/1/92

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-4: Primary eye irritation in rabbits

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423168-17

PC Number:

TEST MATERIAL: HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l

SYNONYM(S): Code: HOE 039866 OH SL06 A302

SPONSOR: Hoechst Celanese Corp., Somerville, NJ

STUDY NUMBER: 88.0408

TESTING FACILITY: Pharma Research Toxicology and Pathology, Frankfurt, Germany

TITLE OF REPORT: Testing for Primary Eye Irritation Study in the Rabbit

AUTHOR(S): U. Milbert and K. Leist

STUDY COMPLETED: March 25, 1988

CONCLUSIONS: Classified as non-irritating.

CORE CLASSIFICATION: Core Guideline. This study satisfies the Guideline requirements (81-4) for a primary eye irritation study.

TOXICITY CATEGORY: III (Caution).

A. MATERIALS

Test Compound

Test material: HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l
Identification number: Code: HOE 039866 OH SL06 A302
Active ingredient: Glufosinate ammonium
Formulation: Glufosinate ammonium 6.0% w/w
Purity: See above
Physical description: Blue liquid
Storage condition: In darkness at 4°C
Stability: Analysis Feb. 22, 1988

Dose levels: 0.1 ml liquid (undiluted)

3. Test Animals

Species: Rabbit
Strain: New Zealand Albino
Source: HOECHST AG, Kastengrund, Germany
Number of animals: 9
Sex: Unspecified
Age: 3-5 months
Mean body weight: 1.8-4.2 kg
Environmental conditions: Temperature 20±3°C
Humidity 50±20%
Photoperiod 12 hours

B. TEST PERFORMANCE

1. Eye Examination: Eyes were examined 24 hours prior to testing with fluorescein sodium ophthalmic solution. Only healthy animals were used.

2. Test Material Application: The test substance was placed in the lower conjunctival sac of the left eye of each animal. The right eye of each animal served as the untreated control. After 1 minute of exposure, 3 of the 9 treated eyes were washed with saline solution. The other 6 animals were washed at 24 hours.

3. Observation Period: 30-60 minutes; 1, 24, 48 and 72 hours; and 7, 14 and 21 days

4. Scoring System: Eyes were examined and scored for ocular lesions using the Draize scoring system.

C. REPORTED RESULTS: A summary of ocular effects is presented below:

Summary of Incidence of Positive[a] Ocular Effects

	Observation Intervals								
	Hour				Day				
	1	24	48	72	4	7	10	14	17
Cornea									
Opacity	0/9	2/9	0/9	-	-	-	-	-	-
Iris									
Iritis	2/9	1/9	0/9	-	-	-	-	-	-
Conjunctivae									
Redness	0/9	1/9	0/9	-	-	-	-	-	-
Chemosis	0/9	-	-	-	-	-	-	-	-

[a]The following grades for each tissue are considered positive:

Opacity (Density) - Grades 1, 2, 3, and 4
Iris - Grades 1 and 2
Conjunctivae (Redness) - Grades 2 and 3
(Chemosis) - grades 2, 3, and 4

24 hour wash maximum irritancy index = 9.67 (non-irritating)
1 minute wash maximum irritancy index = 3.33 (non-irritating)

All signs were clear by 48 hours.

Based on these findings HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l is classified as Toxicity Category: III (Caution).

D. REVIEWERS' COMMENTS: We assess in agreement with the study author that HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l had a maximum irritancy index of 9.67 for eyes washed at 24 hours and was non-irritating to rabbits.

E. QUALITY ASSURANCE MEASURES: Was the test performed under GLPs? yes. A Quality Assurance Statement was signed May 3, 1988.

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DER133-100

DATA EVALUATION REPORT

HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l

Study Type: Primary Dermal Irritation in Rabbits

Prepared for:

Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by:

Clement International Corporation
9300 Lee Highway
Fairfax, VA 22031

Principal Reviewer Laura Kolb Date 9/23/92
Laura Kolb

QA/QC Manager William L McLellan Date 9/24/92
William McLellan

Contract Number: 68D10075
Work Assignment Number: 1-133
Clement Number: 1-133-199
Project Officer: James Scott

2.

Approved by:

EPA Reviewer:

Signature: Sam D. Brendel
Date: 11/19/92

DATA EVALUATION REPORT

STUDY TYPE: Guideline 81-5: Primary dermal irritation in rabbits

EPA IDENTIFICATION NUMBERS

Tox Chem. No.:

MRID No.: 423168-18

PC Number:

TEST MATERIAL: HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l

SYNONYM(S): Code: HOE 039866 OH SL06 A302

SPONSOR: Hoechst Celanese Corp., Somerville, NJ

STUDY NUMBER: 88.0407

TESTING FACILITY: Pharma Research Toxicology and Pathology, Frankfurt, Germany

TITLE OF REPORT: Testing for Primary Dermal Irritation in the Rabbit

AUTHOR(S): U. Milbert and K. Leist

STUDY COMPLETED: March 29, 1988

CONCLUSIONS: Primary Irritation Index: 0.66 (Slightly Irritating)

CORE CLASSIFICATION: Core Guideline. This study satisfies the Guideline requirements (81-5) for a primary dermal irritation study.

TOXICITY CATEGORY: ~~IV~~ III (Caution)

A. MATERIALS

Test Compound

Test material: HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l
Identification number: Code: HOE 039866 OH SL06 A302
Active ingredient: Glufosinate ammonium
Formulation: Glufosinate ammonium 6.0% w/w
Purity: See above
Physical description: Blue liquid
Storage condition: In darkness at 20°C
Stability: Date of Analysis: Jan. 15, 1988

Dose levels: 0.5 mL liquid (undiluted)

3. Test Animals

Species: Rabbit
Strain: New Zealand Albino
Source: HOECHST AG, Kastengrund, Germany
Number of animals: 6
Sex: Unspecified
Age: 3-5 months
Mean body weight: 1.6 - 2.5 kg
Environmental conditions: Temperature: 20 ± 3°C
Humidity: 50 ± 20%
Photoperiod 12 hours

B. TEST PERFORMANCE

1. Skin Preparation: The day before testing, the dorsal area of the trunk of each animal was clipped. Only healthy animals were used.

2. Test Material Application: The test substance was applied beneath a piece of surgical plaster with a 2.5 x 2.5 cm cellulose patch, which was secured by a semi-occlusive bandage. After 4 hours of exposure, the patch was removed and residual test material was removed with tap water.

3. Observation Period: 30-60 minutes; 24, 48 and 72 hours; and 7 days

4. Scoring System: Primary Irritation Index

C. REPORTED RESULTS: Slight to moderate erythma was present up to 72 hours. The surface of the treated skin was dry and chapped, with peeling of fine or coarse scales.

These values correspond to a Primary Irritation Score of 3.3 (Slightly Irritating). Based on this score, HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l, was classified as Toxicity Category: ~~IV~~ III (Caution).

D. REVIEWERS' COMMENTS: We assess in agreement with the study author that 0.5 ml of undiluted HOE 039866 - Liquid, Water-Soluble Concentrate 60 g/l was slightly irritating to rabbits.

E. QUALITY ASSURANCE MEASURES: Was the test performed under GLPs? yes
A Quality Assurance Statement was signed May 31, 1988.

24.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6)

Product Manager: 23
MRID No.: 423168-19

Reviewer: I. Blackwell
Report Date: 4-13-91
Report No.: A45327

Testing Laboratory: Pharma Research Toxicology and Pathology
Author(s): Dr. K.-H. Diehl, and Dr. K.-H. Leist

Quality Assurance (40 CFR §160.12): Included

Test Material: HOE 039866 OH SL06 A302 (Arise Herbicide)
Positive Control Material: not specified

Species: Pirbright-White guinea pig
Weight: 310 to 415 g **Age:** ≈ 10 weeks
Source: HOECHST AG, Kastengrund, SPF breeding colony

Method: Modified Buehler Method

Summary:

1. **This Product is / is not a dermal sensitizer.**

2. **Classification:** supplementary

Procedure (Deviation From §81-6):
- Induction was conducted using the highest non-irritating concentration.
- Irritation screening used only test material concentrations at or below 50%.
- No positive control testing was conducted.
- The irritation was scored using the Draize Scale.

Results: Irritation during induction progressed from no irritation after treatments 1 and 2 to moderate-to-severe erythema in 1/20, well-defined in 1/20, and very slight erythema in 7/20 after the 9th induction treatment.

No irritation was displayed 24 or 48 hours after challenge.

PC Code ? File Last Updated Current date 11/19/92

Study/Study #/Animal/Lab Date	Material	MRID No.	Results	Tox. Cat.	Core Grade
acute oral toxicity / A38670 / rat / Pharma Research Toxicology and Pathology / 5-19-88	Glufosinate-ammonium: Ammonium-DL-homoalanine-4-yl-(methyl) phosphinate 5.78%	423168-14	LD_{50} (mg/kg) males > 5000 females 2000<x<4000	III	guide
acute dermal toxicity / A38670 / rat / Pharma Research Toxicology and Pathology / 4-7-88		423168-15	LD_{50} (mg/kg) males > 4000 females > 4000	III	min.
acute inhalation toxicity / A46005 / rat / Pharma Development Toxicology / 5-9-91		423168-16	LC_{50} males = 2.45 mg/L females = 2.01 mg/L combined= 2.19 mg/L	III	guide
primary eye irritation / A38467 / rabbit / Pharma Research Toxicology and Pathology / 3-5-88		423168-17	Corneal and iritis opacity in 2/9, and redness in 1/9 clearing by 48 hours.	III	guide
primary dermal irritation / A38513 / rabbit / Pharma Research Toxicology and Pathology / 3-29-88		423168-18	Slight to moderate irritation was present to 72 hours.	III	guide
dermal sensitization / A45327 / guinea pig / Pharma Research Toxicology and Pathology / 4-13-91		423168-19			sup.